Japan: New notice of the revision of ISO 13485 on QMS surveillance

In July 29th 2016, MHLW released the administrative circular “Handling of the revision of ISO 13485 in QMS surveillance”.

Since ISO 13485:2016 became effective from March 1st 2016 and transition period from ISO13485:2003 was set to be 3 years, MHLW stated relationship between Chapter 2 of MHLW Ministerial Ordinance No. 169 (hereinafter “QMS Ordinance”) and each clause of ISO 13485:2016 as follows:

1) The target manufacturers
   The manufacturer to apply for new or partial change of Pre-market Approval or Pre-market Certification

2) The target product
   Medical Devices and In-vitro Diagnostic Drug

3) Before change and after change
   After change, when the manufacturer performs product management and quality management appropriately based on ISO13485:2016, for the moment, MHLW considers that they comply with QMS Ordinance Chapter 2. Because ISO 13485:2016 has not changed the management and the basic elements of configuration for the quality management and supervision system based on the process approach that is specified by ISO13485:2003.

   Before change, MHLW has regulated the consistency of QMS Ordinance Chapter 2 and ISO 13485:2003 by two MHLW notifications which were released in 2014. (Chapter 2 is identical to Clauses 4 to 8 of ISO 13485:2003) These notifications are not revised this time.

(End)